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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,613	02/10/2004	Tomoko Takeshita	HIRA.0141	1668

7590 12/21/2005  
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EXAMINER
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SHAHER, SHULAMITH H

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/774,613	<b>Applicant(s)</b> TAKESHITA ET AL.	
	<b>Examiner</b> Shulamith H. Shafer, Ph.D.	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/10/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1647

### **Detailed Action**

#### ***Status of Application, Amendments, And/Or Claims***

The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Shulamith H. Shafer, Art Unit 1647.

Applicant's response to the Non-Final Office Action of 26 July 2005 has been received on 25 October 2005 and entered in full. Claims 7-12 have been withdrawn as directed to a non-elected invention. Claims 1-6 are pending and stand rejected. Amendments to claims 1 and 5 received on 25 October 2005 have been entered in full. Applicant refers to a figure attached as Exhibit A, but this Office cannot respond to information contained in the figure, as it did not accompany the response of 25 October 2005.

The Applicant's arguments filed on 25 October 2005 will be responded to herein. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### **Rejections Withdrawn**

#### ***35 U.S.C. § 112, First Paragraph:***

Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement by introducing new matter by reciting GPCRs "that couples with G-proteins other than Gq subtype G-proteins" is withdrawn in response to amendment to the claim.

### **Rejections Maintained**

#### ***35 U.S.C. §§ 101 and 112, First Paragraph***

The rejection of claims 1-6 under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial utility or well established utility is maintained for reasons of record in the previous office action of 26 July 2005. The rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph is also maintained for reasons of record in the previous office action of 26 July 2005. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant asserts that the Examiner's rejection under 35 U.S.C. § 101 is contrary to the established patent examining procedure, as it constituted a piecemeal examination and deprived Applicant of the opportunity to have the application examined in a timely manner. Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons. The instant office action of 26 July 2005 was made non-final to allow applicant adequate time and opportunity to respond.

Applicant traverses the rejection by asserting that the methods and cells of the instant invention have specific and credible utility for identifying a ligand for the GPCR with unknown functions. Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons. Credibility has not been questioned. A specific utility needs to be specific to the claimed subject matter. The asserted utility is not specific, since any receptor protein can be used in an assay to identify binding partners. Any GPCR transfected into an isolated host cell can be utilized to identify ligands that bind to the given GPCR. Transfecting isolated host cells with genes coding for GPCRs of unknown function and screening for binding partners is not a specific utility; it is an invitation to experiment. The only immediate, apparent utility for the instant invention would be to further characterize a GPCR of unidentified function.

Applicant asserts that identifying ligands for potential new therapeutics constitutes a substantial “real world” utility, as it is “one of the most important facets of drug discovery”. Applicant’s arguments have been fully considered but are not found to be persuasive for the following reasons. The specification has not identified any specific disease state or condition to be diagnosed or treated by the ligands identified by the methods of the instant invention. In the absence of a clear nexus between a specific disease state or pathological condition and the recited GPCR, what diseases could be treated with the candidate compounds identified by the claimed method? If further research is required to establish such a relationship, what would the “real world” utility of the method of the instant invention be?

**35 U.S.C. § 112, First Paragraph:**

Rejection of Claim 5 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement by introducing new matter by reciting GPCRs “that couples with G-proteins other than Gq subtype G-proteins” is maintained. Applicant’s attempt to amend claim and remove the phrase “that couples with G-proteins other than Gq subtype G-proteins” is noted. However the phrase is still present in the claim as submitted by the applicant. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is maintained.

**35 U.S.C. § 102**

The rejection of claims 1-2 and 5-6 under 35 U.S.C. § 102(b) as being anticipated by Nakamura et al., (1996, J Biochem. 120:996-1001) is maintained for reasons of record in the previous office action of 26 July 2005.

Applicant traverses this rejection and asserts that Nakamura fails to teach or disclose each and every limitation of claims 1-2 and 5-6. Applicant argues the

Art Unit: 1647

methodology of the instant invention can “elucidate a function of the GPCR by using a single assay technique, including an assay based on changes in Ca-dependent Cl current” and that Nakamura does not “teach or disclose coexpression of GPCRs with unknown functions and chimeric G-proteins”. Applicant’s arguments have been fully considered but are not found to be persuasive for the following reasons. Assertion of intended use of claimed invention is not given any patentable weight. Furthermore, Applicant’s response is arguing limitations that are not recited in the claims. The claims of the instant invention are drawn to a method comprising the following steps:

1. Transfecting isolated host cells with genes encoding G-protein coupled receptors and genes encoding a chimeric Gq $\alpha$  subunit consisting of, from N-terminus to C-terminus, amino acid sequence of Gq $\alpha$  or G<sub>11</sub> $\alpha$  subunit N-terminal region and amino acid sequence of G<sub>14</sub> $\alpha$ , G<sub>15</sub> $\alpha$ , or G<sub>16</sub> $\alpha$  subunit C-terminal region.
2. Treating or culturing cells under conditions to allow the expression of above transfected genes.

Claims 1-2 and 5-6 do not recite the limitations of any specific GPCR of known or unknown function, nor any specific G-protein from any specific source. The claims also do not disclose any specific downstream signal transduction events, such as changes in the Ca-dependent Cl current, that need be activated upon binding of ligand to GPCR. Nakamura et al disclose construction of G<sub>L1</sub> $\alpha$ /G<sub>L2</sub> $\alpha$  chimeras (page 997, paragraph 2). The reference teaches that the G<sub>L1</sub> $\alpha$  subunit is the bovine homologue of mouse G<sub>14</sub> $\alpha$  subunit and that the G<sub>L2</sub> $\alpha$  subunit is the bovine homologue of mouse G<sub>11</sub> $\alpha$  subunit (page 996, abstract). Figure 1 (page 998) teaches various chimeric constructs some of which consist of amino acids of the G<sub>L2</sub> $\alpha$  subunit (a G<sub>11</sub> $\alpha$  subunit) at the N-terminal end, and amino acids of the G<sub>L1</sub> $\alpha$  subunit (a G<sub>14</sub> $\alpha$  subunit) at the C-terminal end, meeting the limitations of the recited claims (2 and 6) of the instant invention. Nakamura et al teach the injection of specific mRNAs encoding mGlu-R1 (a GPCR) and the chimeric proteins into *Xenopus* oocytes (page 997, column 2, paragraph 3) and the expression of these genes in the host cells (page 997, column 1, paragraph 1). Thus, Nakamura et al. teach

Art Unit: 1647

the methods of claim 1 and 2 and the "foreign protein-expressing cells" recited in claims 5 and 6. Therefore, Nakamura et al. teach all the limitations of claims 1, 2, 5 and 6. Applicant asserts that Nakamura et al. investigate what type of chimera between  $G_{L1\alpha}$  and  $G_{L2\alpha}$  coexpressed with mGluR1 could effectively activate PLC. The motivation or goal of the artisan carrying out these method steps is immaterial. The method steps are the important teachings of the cited references.

The teachings of the Hermans reference are rendered moot by Applicant's amendments of the claims. In the response of 25 October 2005, Applicant refers to a figure in Exhibit A. The arguments or evidence presented in Exhibit A cannot be considered, as this document was not included with Applicant's response of 25 October 2005.

### **35 U.S.C. § 103**

The rejection of claims 3 and 4 as being unpatentable over Nakamura et al., (1996, J Biochem. 120:996-1001) under 35 U.S.C. § 103 and MPEP § 2144.05 is maintained for reasons of record in the previous office action of 26 July 2005.

Applicant traverses this rejection and asserts that Nakamura et al. does not teach or suggest co-expression of GPCRs with unknown functions and chimeric G-proteins. However, as discussed above, the claims do not recite the limitations of "GPCRs with unknown functions" and Applicant is arguing limitations not disclosed in claims. Nakamura et al. does teach co-expression of mGlu-R1 (a GPCR) and chimeric G-proteins. As discussed above, the motivation of Nakamura et al. is not an issue in determining applicable art. The claims are drawn to methods of introducing genes encoding a GPCR and a chimeric proteins and cells co-expressing the products of such genes. The teachings of Nakamura et al. disclose these limitations.

As to MPEP § 2411, Applicant is correct that this section deals with biological deposits and is not relevant to the § 103 rejection. The typographical error is regretted. Applicant is referred to **MPEP § 2144.05** for the pertinent information.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Elizabeth C. Kemmerer*

SHS

ELIZABETH KEMMERER  
PRIMARY EXAMINER